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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,956	02/08/2001	Peter James Woolf	A0000133-01-CA	5820
909	7590	11/17/2004	EXAMINER	
PILLSBURY WINTHROP, LLP P.O. BOX 10500 MCLEAN, VA 22102			MARSCHER, ARDIN H	
			ART UNIT	PAPER NUMBER
			1631	
DATE MAILED: 11/17/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/778,956	Applicant(s) WOOLF ET AL.	
	Examiner Ardin Marschel	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/29/04 & 9/10/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27, 29, 33 and 40-45 is/are rejected.
- 7) ☒ Claim(s) 28, 30-32, & 34-39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>8/11/04</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on 7/29/04 and 9/10/04, has been entered.

Applicants' arguments, filed 7/29/04 and 9/10/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

TITLE

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title only cites a method whereas the pending claims include methods, systems, and machine-readable media.

VAGUENESS AND INDEFINITENESS

Claims 1-22 and 42-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In independent claims 1 and 16, and claims dependent therefrom due to their dependence, a relative term is set forth as "higher" in the phrase "higher number of different genes or proteins" which causes the claims to be vague and indefinite due to lacking any indication as to what this relative term refers to as being "higher".

Clarification via clearer claim wording is requested.

In the preambles of independent claims 1 and 9 the practice of the claims may be interpreted as being directed to a plurality of "biological cells". See, for example, line 2 of claim 1. In the actual method steps, such as lines 3-10 of instant claim 1 there is no corresponding plural "cells" limitation. In line 3 of instant claim 1 the expression data is described as being "cell-based" which at best only cites a single cell. It may be assumed that multiple cells are meant, however, the requirement for such an assumption support this rejection that the claim is not clear and concise as required by 35 U.S.C. § 112, second paragraph. Claims which dependent from claims 1 or 9 also contain this unclarity due to their dependence. Clarification via clearer claim wording is requested.

PRIOR ART

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 9, 16, 23-27, 29, 33, and 40-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramm et al. (P/N 6,345,115); taken in view of Agrafiotis et al. (P/N 6,421,612).

Ramm et al. summarizes the invention in the title and abstract as being directed to digital imaging systems for assays of various types, such as assays using arrays of targets. Such assay types to which the imaging practice of said disclosure are directed are reviewed in Ramm et al. in columns 1-11 to include a wide variety of such assays. Such assay types include gene expression assays for genetic analyses wherein arrays of targets are imaged as stated in column 2, lines 54-64, as also utilized in the instant claims, for example, instant claim 1, lines 3-5. These assays include cell-based assay types including the effects of compounds thereon as set forth in the reference in column 2, lines 35-38, as also cited in instant claim 1, line 3-4. The effects of compounds on cells are well known to be assayed via control versus treated cells in Biotechnology of this type such as cited in instant claim 1, line 3. The quantification of gene expression levels or to localize relevant sequences are cited as objectives of such assays in said column 2 citation which describes the direction and magnitude limitations for gene expression data analysis as in instant claim 1, lines 3-5. In order to localize data spots on such arrays, analysis of imaging data is required so as to determine intensity levels of signal data properly as described in Ramm et al. in column 9, line 60, through column

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10, line 39. Each of such data signal points are reasonably a C data point as set forth in instant claim 1. Further statistical analysis is described for such data in column 10, line 40, through column 11, line 15. In column 11, lines 1-15, the present invention of Ramm et al. is described as modeling and correcting measurements to result in low error variation in order to achieve acceptable accuracy in quantifying well data. This low error variation evaluation is an evaluation of the confidence level of predicted values as required in the last line of instant claim 1. The usage of a fuzzy logic algorithm for positioning and image analysis in Ramm et al. is set forth in column 10, lines 30-33. Ramm et al. lacks specifics of what is practiced in such fuzzy logic algorithms thus motivating someone of ordinary skill in the art to look to the prior art for details of fuzzy logic algorithm practice.

Agrafiotis et al. describes the analysis of a variety of chemical entities for chemical, bioactive, etc. properties as summarized in the title, abstract, and General Overview in column 6, lines 56-65. A variety of combinatorial compound sets are described as analyzed in Agrafiotis et al., however, the analysis of Agrafiotis et al. is not limited to combinatorial compound synthesis practice due to broader analysis subject matter including biochemical and biological analyses as set forth in column 9, lines 22-65. Cellular activity analyses, of which gene expression data is reasonably a type, bioavailability, etc. are included as assay types in column 9, lines 57-65. Clearly the intent of the Agrafiotis et al. methodology is to be generic to cover a wide range of assay data analyses thus motivating and suggesting such analyses from the prior art as, for example, discussed above in Ramm et al. In Agrafiotis et al. in column 21, line

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33, through column 23, line 5, summarizes the usage of fuzzy logic algorithms for data analysis including genotypically or phenotypically comparing models for predictions thereof in column 23, lines 2-5, as also cited in instant claim 1. The most important features of molecules are also analyzed via principle component analysis, scaling, etc. as described in column 21, lines 50-54, which is reasonably a heuristic rule application as in instant claim 1, lines 7-8. Crisp data additionally is discussed as being usually utilized as an option in column 21, lines 55-61, as also utilized for the analysis in instant claim 1. Besides fuzzifying data, the defuzzifying of data for said prediction of result of the analysis of Agrafiotis et al. is set forth in column 22, lines 6-12, as cited in the penultimate line of instant claim 1.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the array assay technology of Ramm et al. wherein fuzzy logic algorithm analysis is motivated from the prior art, wherein Agrafiotis et al. sets forth details of fuzzy logic algorithm analyses as instantly claimed. This combination of references results in a reasonable expectation of success to perform the methodology of the instant invention as in the above listed instant claims. Other instant claims beyond claim 1 are obvious for reasons set forth above. For example, instant claims 9 and 16 cite the same practices as instant claim 1 in a system or computer readable medium which is suggested at least by the title of Agrafiotis et al., as well as the automation description in the abstract, in the above summarized combination of references. The predicting and data matching of instant claims 23-27 and 29 have been discussed above in modeling descriptions in the reference. Heuristic analysis which is

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only performed via scaling etc. rules as in instant claim 33 has been described above.

The gene expression or nucleic acid analysis of instant claims 40-45 have been described above regarding gene expression analysis.

CLAIM OBJECTIONS

Claims 28, 30-32, and 34-39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

INFORMALITIES

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See the hyperlink in the specification on page 12, line 15. Applicants are required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 12, 2004

John D. Woodward 11/12/04